

DRONCIT CANINE CESTOCIDE- praziquantel tablet
Bayer HealthCare, LLC Animal Health Division

Droncit®
(praziquantel)

Canine Cestocide Tablets

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

Each tablet contains 34 mg praziquantel.

DESCRIPTION:

Droncit® (praziquantel) Canine Cestocide Tablets are sized for easy oral administration to either adult dogs or puppies. The tablets may be crumbled and mixed with the feed.

INDICATIONS:

Droncit® (praziquantel) Canine Cestocide Tablets are indicated for the removal of the following canine cestodes: *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*.

CONTRAINDICATIONS:

There are no known contraindications to the use of praziquantel in dogs.

ACTION:

Droncit® (praziquantel) is absorbed, metabolized in the liver and excreted in the bile. Upon entering the digestive tract from the bile, cestocidal activity is exhibited.¹ Following exposure to praziquantel, the tapeworm loses its ability to resist digestion by the mammalian host. Because of this, whole tapeworms, including the scolex, are very rarely passed after administration of praziquantel. In many instances only disintegrated and partially digested pieces of tapeworms will be seen in the stool. The majority of tapeworms are digested and are not found in the feces.

USE DIRECTIONS:

Droncit® (praziquantel) Canine Cestocide Tablets may be administered directly per os or crumbled and mixed with the feed. The recommended dosage of praziquantel varies according to body weight. Smaller animals require a relatively larger dosage because of their higher metabolic rate. The optimum dose for each individual animal will be achieved by utilizing the following dosage schedule:

Dogs and Puppies*

5 lbs. and under	½ tablet
6-10 lbs.	1 tablet
11-15 lbs.	1 ½ tablets
16-30 lbs.	2 tablets
31-45 lbs.	3 tablets
46-60 lbs.	4 tablets

Over 60 lbs.

5 tablets max

* Not intended for use in puppies less than 4 weeks of age.

FASTING:

The recommended dosage of praziquantel is not affected by the presence or absence of food in the gastrointestinal tract, therefore, **FASTING IS NEITHER NECESSARY NOR RECOMMENDED.**

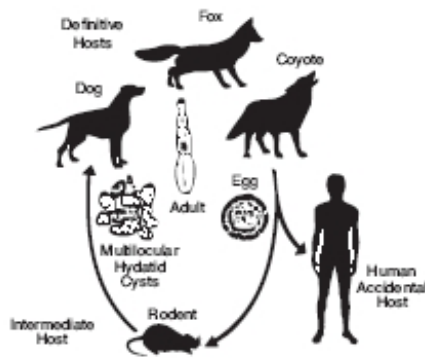
RETREATMENT:

For those animals living where reinfections are likely to occur, clients should be instructed in the steps to optimize prevention, otherwise, retreatment may be necessary. This is true in cases of *Dipylidium caninum* where reinfection is almost certain to occur if fleas are not removed from the animal and its environment. In addition, for control of *Echinococcus multilocularis*, a program of regular treatment every 21 to 26 days may be indicated (see *E. multilocularis* section below).

ECHINOCOCCUS MULTILOCULARIS:

Echinococcus multilocularis is a tapeworm species ordinarily considered to be found in wild canids, including foxes, coyotes and wolves. The parasite has also been identified in domestic dogs and cats and potentially is a serious public health concern by involving humans as accidental intermediate hosts.

The life cycle of the parasite is based on a predator-prey relationship, as depicted.



The adult tapeworm is small (1-4 mm) and resides in the intestinal tract of the definitive host (wild or domestic canids). Eggs from the adult tapeworm are shed in the feces of the infected canid. Rodents such as mice and voles serve as the intermediate host for *E. multilocularis*. Eggs ingested by rodents develop in the liver, lungs and other organs to form multilocular cysts. The life cycle is completed after a canid consumes a rodent infected with cysts. After ingestion of an infected rodent, larvae contained within the cyst develop into adult tapeworms in the intestinal tract of the canid. Eggs may begin to be passed in the feces of the canid approximately 28 days later.

This parasite poses a serious public health problem because of the possibility for human involvement in the lifecycle. If eggs shed by an infected canid are accidentally ingested, a highly pathogenic condition (Alveolar Hydatid Disease) results from development of the cyst stage in humans.

The original geographic distribution of *E. multilocularis* was primarily confined to northern areas of North America. Current evidence indicates migration of the parasite well into the continental United States.^{2,3}

Domestic dogs living in *E. multilocularis* endemic areas that roam freely with the opportunity to catch wild rodents are at risk for infection. Pet owners should be advised on how to minimize this risk. Proper restraint of roaming dogs should be encouraged, along with regular treatment with Droncit tablets,

following the established dosage schedule (above) and the precautions indicated below.

Additional information on the life cycle and epidemiology of this parasite is available in veterinary parasitology texts.^{4,5}

DIAGNOSIS:

Diagnosis of *E. multilocularis* in canids is difficult. The adult tapeworm produces no clinical signs of infection. Tapeworm segments (proglottids) are usually not observed in the feces. *E. multilocularis* eggs, observed using microscopic fecal examination procedures, are similar in appearance to the common taeniid species of canids such as *Taenia pisiformis*.

Assistance in the diagnosis of *E. multilocularis* may be available from a state veterinary diagnostic laboratory. Additional information regarding areas where *E. multilocularis* is suspected or has been confirmed may be obtained from area veterinary schools or the Centers for Disease Control in Atlanta, GA.

TREATMENT:

Dogs infected with *E. multilocularis* should be treated to prevent exposure of humans to infective eggs and to reduce perpetuation of the parasite's life cycle.

The dosage of Droncit tablets for removal of *E. multilocularis* is the same as that indicated for the removal of the other tapeworm species listed on the label. Laboratory efficacy studies have demonstrated the recommended dosage is 100% efficacious for removal of this tapeworm.

Under condition of continual exposure to wild rodents, retreatment of the dog at 21-26 day intervals is recommended to prevent the shedding of infectious eggs.

PRECAUTIONS:

Strict hygienic precautions should be taken when handling dogs or feces suspected of harboring *E. multilocularis*. Infected dogs treated for the first time with Droncit tablets and dogs treated at intervals greater than 28 days may shed eggs in the feces after treatment. The animal should be held in the clinic during this interval and all feces should be incinerated or autoclaved. If these procedures are not possible, the eggs can be destroyed by soaking the feces in a sodium hypochlorite (bleach) solution of 3.75% or greater.⁶ All areas where the animal was maintained or in contact with should be thoroughly cleaned with sodium hypochlorite and allowed to dry completely before reuse.

ANIMAL SAFETY:

The safety index has been derived from controlled safety evaluations, clinical trials and prior approved use in foreign countries. Dosages of 5 times the labeled rate at 14 day intervals to dogs as young as 4 weeks did not produce clinical signs of toxicity. No significant clinical chemistry, hematological, cholinesterase, or histopathological changes occurred. Symptoms of gross overdosage include vomiting, salivation, diarrhea and depression.

PREGNANCY:

Droncit® (praziquantel) has been tested in breeding and pregnant dogs. No adverse effects were noted.

ADVERSE REACTIONS:

Seven instances (3.2%) of either vomiting, anorexia, lethargy or diarrhea were reported during the field trials in which 218 dogs were administered Droncit® Canine Cestocide Tablets. The investigators rated

these as non-significant.

For medical emergencies or to report adverse reactions, call 1-800-422-9874.

WARNING:

Keep out of the reach of children. Not for human use. For customer service or to obtain product information, including Material Safety Data Sheet, call 1-800-633-3796.

STORAGE:

Store at less than or equal to 25°C (77°F)

HOW SUPPLIED:

Bottle of 50 and 150 scored tablets.

Each scored tablet contains 34 mg praziquantel.

Product Code 08713157-182899 — 50 Tablets

Product Code 08713238-186099 — 150 Tablets

REFERENCES:

¹Andrews, P. Pharmacokinetic Studies with Droncit® in Animals Using a Biological Assay. *Veterinary Medical Review* 2/76: 154-165.

²Hildreth, M.B., Johnson, M.D. and Kozacos, K.R. 1991. A Zoonosis of Increasing Concern in the United States. *Compendium for Cont Ed* 13(5): 727-740.

³Lieby, P.D., Carney, W.P., and Woods, C.E. 1970. Studies on Sylvatic Echinococcosis. III. Host Occurrence and Geographic Distribution of *Echinococcus multilocularis* in the North Central United States. *J Parasit* 56(6): 1141-1150.

⁴Georgi, J.R. and Georgi M.E. 1990. *Parasitology for Veterinarians*. W.B. Saunders Co. 118-138.

⁵Soulsby, E.J.L. 1982. *Helminths, Arthropods and Protozoa of Domesticated Animals*. 7th Edition. Lea & Febiger 118-138.

⁶Craig, P.S. and McPharson, C.N.L. 1988. Sodium Hypochlorite as an Ovicide for *Echinococcus*. *Ann Trop Med and Parasit* 82(2): 211-213.

Bayer

Bayer HealthCare LLC, Animal Health Division
Shawnee Mission, Kansas 66201 U.S.A.
NADA 111-798, Approved by FDA
Made in Germany

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19065

Principal Display Panel – 50 Tablets

Lot No.:
Exp. Date:
B 2 F 9

For Removal Of *Dipylidium caninum*, *Taenia pisiformis*,
Echinococcus granulosus and For Removal And Control Of
Echinococcus multilocularis

Tablets may be given directly or crumbled and offered with the
feed. FASTING IS NEITHER NECESSARY NOR RECOMMENDED.
STORAGE: Store at less than or equal to 25°C (77°F).
See package leaflet for complete details.



Droncit®
(praziquantel)
 **34**
Canine Cestocide Tablets

EACH TABLET CONTAINS: 34 mg praziquantel.
CAUTION: Federal (U.S.A.) law restricts this drug to use by
or on the order of a licensed veterinarian.
WARNING: KEEP OUT OF REACH OF CHILDREN.

Bayer 50 Tablets

Bayer HealthCare LLC, Animal Health Division Shawnee Mission,
Kansas 66201, USA NADA 111-798, Approved by FDA
Made in Germany

DOSAGE AND ADMINISTRATION: Administer orally to
dogs as follows:

Body Weight (lbs.)	No. of Tablets
5 and under	0.5
6-10	1.0
11-15	1.5
16-30	2
31-45	3
46-60	4
over 60	5 tablet max.

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08713157-182899 19066 08954529, R.2

Droncit® **(praziquantel)** **34** **Canine Cestocide Tablets**

EACH TABLET CONTAINS: 34 mg praziquantel.

CAUTION: Federal (U.S.A.) law restricts this drug to use by
or on the order of a licensed veterinarian.

WARNING: KEEP OUT OF REACH OF CHILDREN.

BAYER **50 Tablets**
Bayer HealthCare LLC, Animal Health Division Shawnee Mission,
Kansas 66201, USA NADA 111-798, Approved by FDA
Made in Germany

Principal Display Panel – 150 Tablets

Lot No.:
Exp. Date:
B3F0

For Removal Of *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and For Removal And Control Of *Echinococcus multilocularis*
Tablets may be given directly or crumbled and offered with the feed.
FASTING IS NEITHER NECESSARY NOR RECOMMENDED.
STORAGE: Store at less than or equal to 25°C (77°F).
See package leaflet for complete details.



EACH TABLET CONTAINS: 34 mg praziquantel.
CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.
WARNING: KEEP OUT OF REACH OF CHILDREN.

Bayer 150 Tablets

Bayer HealthCare LLC, Animal Health Division Shawnee Mission,
Kansas 66201, USA NADA 111-798, Approved by FDA
Made in Germany

DOSE AND ADMINISTRATION: Administer orally to dogs as follows:

Body Weight (lbs.)	No. of Tablets
5 and under	0.5
6-10	1.0
11-15	1.5
16-30	2
31-45	3
46-60	4
over 60	5 tablet max.

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Droncit®
(praziquantel)
34

Canine Cestocide Tablets

EACH TABLET CONTAINS: 34 mg praziquantel.

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

WARNING: KEEP OUT OF REACH OF CHILDREN.

BAYER **150 Tablets**

Bayer HealthCare LLC, Animal Health Division Shawnee Mission,
Kansas 66201, USA NADA 111-798, Approved by FDA
Made in Germany

DRONCIT CANINE CESTOCIDE

praziquantel tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0859-2130
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZIQUANTEL	34 mg

Product Characteristics

Color	WHITE (White to off-white)	Score	2 pieces
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Shape	ROUND	Size	13mm	
Flavor		Imprint Code	Droncit;34	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0859-2130-01	50 in 1 BOTTLE		
2	NDC:0859-2130-02	150 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NADA	NADA111798		12/11/1981	

Labeler - Bayer HealthCare, LLC Animal Health Division (152266193)